SYBRON DENTAL SPECIALTIES

K031484

JUL 0 3 2003

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: May 2003

Device Name:

- Trade Name – Stand Out
- Common Name – Dental Impression Material
- Classification Name – Impression Material, per 21 CFR § 872.3660

Devices for Which Substantial Equivalence is Claimed:

- Dentsply Caulk, *Aquasil UltraMonophase/Heavy/LV Smart Wetting Impression Material*

Device Description:

The device is an addition-cure vinyl polysiloxane dental impression material that is used for all crowns and bridges, edentulous and implant impression techniques. Stand Out is a two-part, base/catalyst – paste/paste system. The product is available in two viscosities, Wash and Tray.

Intended Use of the Device:

The intended use of Stand Out is for all crowns and bridges, edentulous and implant impressions.

Substantial Equivalence:

Stand Out is substantially equivalent to other legally marketed devices in the United States. Stand Out functions in a manner similar to and is intended for the same use as Aquasil UltraMonophase/Heavy/LV Smart Wetting Impression Material that is currently manufactured by Dentsply Caulk.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Colleen Boswell
Director, Corporate Compliance
Sybron Dental Specialties, Incorporated
1717 W. Collins Avenue
Orange, California 92867

JUL 0 3 2003

Re: K031484
Trade/Device Name: Stand Out
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Codes: ELW
Dated: May 08, 2003
Received: May 12, 2003

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I - Indications for Use

Ver/ 3 - 4/24/96

Applicant: Kerr Corporation

510(k) Number (if known): K031484

Device Name: Stand Out

Indications For Use:

Stand Out is an addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous and implant impression techniques.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031484

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)